# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/674,815 | 12/07/2000 | Akira Aomatsu | 5836-01-MJA | 5030 |

7590 12/01/2006

Charles W Ashbrook
Warner Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105

| EXAMINER |
|---|
| KWON, BRIAN YONG S |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/674,815 | AOMATSU, AKIRA | |
| | Examiner | Art Unit | |
| | Brian S. Kwon | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *32 and 34-38* is/are pending in the application.

4a) Of the above claim(s) *32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application*

1. By Amendment filed September 28, 2006, claims 34, 35, 36 and 37 have been amended and claims 25-28, 31, 33 and 39 have been cancelled.

2. Claims 34-38 are currently pending for prosecution on the merits of the case. Claim 33 has been withdrawn from further consideration by the examiner as being drawn to the non-elected invention.

### *Summary of Action*

3. The rejection of claims 25-28, 31 and 33-39 under 35 U.S.C. 112, first paragraph, for the scope of the enablement, is not maintained in light of the amendment/remarks.

4. The rejection of claims 25-28, 31, 33 and 39 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is not maintained in light of the amendment/remarks.

5. The rejection of claims 25-27, 29 and 31 under 35 USC 102(b) as being anticipated by Woodruff (US 5084479) is not maintained in light of the amendment/remarks.

6. The rejection of claims 34, 38 and 39 under 35 USC 102(a) as being anticipated by Augart et al. (US 6054482) is not maintained in light of the amendment/remarks.

7. The provisional rejection of claims 34-38 under the judicially created doctrine of double patenting over claims 36-37 of Copending US Application No. 09/674,819 is maintained for the reasons of record since no Terminal Disclaimer has been filed and approved yet in our PTO record.

8. Applicant's amendment changing the scope invention (canceling "the amount of corresponding lactam that is formed in the pharmaceutical composition is less than 0.5% by weight..." and narrowing the scope of the invention to "α amino acid") necessitates a new ground of the rejection in this Office Action.

Applicant's arguments with respect to claims 25-28, 31 and 33-39 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable Robson et al. (US 4126684) in view of Costa et al. (US 5248678) and further in view of Bays et al. (WO 96/11680).

Robson discloses a composition comprising 4-amino-3-substituted butanoic acid derivative such as baclofen, alpha amino acid such as glycine, auxiliary agent (i.e., sorbitol, mannitol, lactose, etc...) and aqueous gelatin solution, wherein said composition is prepared in various dosage forms including tablet, capsule and solution (column 3, line 54 thru column 4, line 11 and Example 2).

Costa and Bays are being supplied as the reference to demonstrate the art recognized functional equivalent of gabapentin and baclofen as GABA agonists.

The teaching of Robson differs from the claimed invention (i) in the substitution of baclofen with known GABA agonist such as gabapentin. To incorporate such teaching into the teaching of Robson, would have been obvious in view of Costa who teaches the use of gabapentin as the functional equivalent to the 4-amino-3-substituted butanoic acid derivative such as baclofen.

As discussed above, gabapentin and baclofen were art-recognized equivalents at the time of the invention. Thus, one of ordinary skill in the art would have found it obvious to substitute baclofen with gabapentin. Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

With respect "the total amount of α amino acid is in the range of 0.001-80 moles per mole of the 4-amino-3-substitued-butanoic acid derivative" (claim 37), optimization of amounts of known active and/or inactive ingredients in a composition or determination of the specific delivery dosage form having optimum therapeutic index is well considered within the skill of the artisan, absent evidence to the contrary. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller, 220 F. 2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).*

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 34-38 are rejected provisionally under the judicially created doctrine of double patenting over claims 36-37 of Copending US Application No. 09/674,819.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claimed composition is overlapping with the claimed scope

of the copending application. Since the interpretation of the instant claim allows for the inclusion of any other unspecified ingredients even in major amounts in said composition, the presence of humectant and auxiliary agent (e.g., neutral amino acid, see page 49, lines 13-15 of the specification) in said composition in the copending application makes obvious the instant claims.

With respect to the determination of concurrent dosage forms, particularly liquid form, those of ordinary skill in the art would have been readily optimized effective dosages forms including liquid dosage forms as determined by good medical practice and the clinical condition of the individual patient. One having ordinary skilled in the art would have been motivated to make such modification to extend the usage of said composition in liquid dosage forms to accommodate patient's preference and needs where the compliance could be improved with effective and well tolerated drug.

## *Conclusion*

12. Applicant's amendment necessitates a new ground of rejection(s) in this Office Action. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. No Claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Patent Examiner
AU 1614

BRIAN-YONG S. KWON
PRIMARY EXAMINER